REMARKS

Applicant wishes to point out that claims 1-5 and 30-37, not claims 1-4 and 30-37 as stated in the Office action, are currently pending in the application. In addition, claim 35 does not contain the error ("franking" verses "flanking") alleged in the Office action. Tables 1 and 3 have been amended by adding sequence identification numbers.

Applicant respectfully submits that the rejection of pending claims in the present application under 35 U.S.C 112, first paragraph, runs contrary to the common sense of the medical profession or a person having ordinary skill in the art. It is based on unsupported, erroneous assertions as well as irrelevant references.

A Common Sense to the Medical Profession:

The medical profession deals with statistics. For example, at the present time, if a cancer-treating drug is found to have a therapeutically effect only on a certain percentage, say 80%, of patients, this would be regarded as a valuable drug. No one with a common sense in the medical profession would say such finding cannot enable a use of the drug to treat cancer patients, merely because it has a less than 100% effective rate in a so-called "unpredictable field".

Just like a treatment method, this common sense equally applies to a detection/diagnosis method. It doesn't require a diagnostic method to be 100% accurate or have a 100% detection rate, particularly at the initial or preliminary stage of a detection or screening process, or as a means to provide one of the multiple criteria necessary for making final diagnosis. If a biomarker is found to be associated with a type of cancer with a statistic significance, no one with a common sense in the medical profession would say such association cannot enable the use of the biomarker as a means for detecting cancer, merely because this biomarker is also found present in some or all normal people, albeit in a statistically significant lower level. For example, an elevated blood sugar level is a biomarker associated with diabetes with a statistically significance, it would make no sense to say it is not

enabled to use blood sugar measurement as one of the tools to detect or confirm the presence of diabetes, merely because everyone's blood has sugar.

The Invention:

The present invention relates to a sensitive method for detecting colorectal cancer, particularly at an early stage. The method is based on the measurement of the blood level of beta-catenin associated RNA, DNA, or both because it was demonstrated for the first time by the present invention that this biomarker is associated with colorectal cancer with a statistically significance. In the specific embodiments disclosed in the present application, these beta-catenin associated nucleic acids could be clearly detected in all the patients tested while they were not detectable (or detected at a significantly lower level) using the measurement methods under the particular conditions disclosed herein. This method is simple with high degree of accuracy, requiring small volumes of blood sample, which can be obtained by non-invasive, normal blood-drawing procedures. The measurement of blood level of the nucleic acid encoding for the protein beta-catenin was well development and within ordinary skill of a person working in this art when the invention was made.

The Cited Evidence:

(A) The Wong Reference

The Wong reference actually corroborates, rather than discredits, the validity and operability of the diagnostic method of the present invention. To say otherwise is to disregard the clear meaning of the paper. Throughout the lengthy prosecution of this case, the Examiner continues a false belief that for a diagnostic method to be enabled there cannot be any overlapping in the biomarker measurement between normal and diseased groups. In order to facilitate the eventual review by the Board, Applicant respectfully requests that the Examiner provide the scientific foundation for such belief, because it has been the Examiner's only argument that the Wong reference supports the non-enablement rejection. The Examiner is required by the law to carry the initial burden to support a *prima facie* case of non-enablement, or the rejection based thereon must be set aside.

(B) The Osmer Reference

Osmer does not, and cannot, demonstrate that a biomarker, like the one of the present invention, is generally not enough for a diagnostic method. Such sweeping conclusion cannot be derived from the reference. In order to facilitate the eventual review by the Board, Applicant respectfully requests that the Examiner set forth the logic by which the Examiner derives such a general sweeping conclusion from the Osmer reference.

(C) The Fleischhacker Reference

The difference between serum and plasma measurements says nothing, one way or the other, about whether a serum measurement would correlate with a certain disease. When the plasma measurement correlates with a disease, there is a strong presumption that a corresponding serum measurement would also similarly correlate. The Fleischhacker reference says nothing to rebut such presumption in the present invention. In order to facilitate the eventual review by the Board, Applicant respectfully requests that the Examiner set forth the logic by which the Examiner derives such a general sweeping conclusion from the Fleischhacker reference that when the plasma measurement of the biomarker correlates with a disease, then the serum measurement of the same biomarker cannot correlates with the diseases.

The Examiner's repeated assertion that "the teachings of Wong, Fleischhacker each suggest that b-catenin amounts would not determine or detect colorectal cancer" amounts to nothing but an illogical assertion similar to the following way of asserting that the sun is of a square shape:

(a) The sun is square because there is a reference that says a lantern is square.
(b) The lantern is light-emitting object, so a light-emitting object is square.
(c) Because the sun is light-emitting object, the sun is square.

This has been the logic the Examiner in the present case uses the references to support the erroneous rejection under 35 U.S.C. §112, first paragraph.

Conclusion

In view of the foregoing remarks, Applicant respectfully submits that the assertion that the present invention is not enabled is based on a false logic and a factual misunderstanding that runs contrary to the common sense of a person having ordinary skill in the art. It further respectfully submits that all the claims pending in the present application are in a condition for allowance. Allowance thereof is thus earnestly solicited.

Respectfully submitted,

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